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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/029,756

12/21/2001

Terry L. Thomas

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04/21/2006

Scully, Scott, Murphy & Presser  
400 Garden City Plaza  
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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/029,756

Applicant(s)

THOMAS, TERRY L.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 48 and 51-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 59 is/are allowed.
- 6) ☒ Claim(s) 48, 51-58 and 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The amendment filed February 3, 2006 has been entered.

Claims 48, 51, 54, 55 and 59 are currently amended.

Claim 60 is newly submitted.

Claims 48 and 51-60 are pending.

### ***Claim Rejections - 35 USC § 112***

Claims 48, 51-58 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons set forth in the prior office action.

1. Applicant's arguments filed February 3, 2006 have been fully considered but they are not persuasive. Applicant asserts that the present invention is based on the identification of the first two delta-6 desaturase sequences from plants. In addition applicants assert that prior to applicants' invention that it was known that all membrane bound desaturases have three histidine-rich sequences, wherein the histidine-rich sequences show homology to other membrane-bound desaturases. Applicant further states that the three histidine boxes from borage and other plant species have distinct sequences and asserts that the sequences in Table 3 compare the histidine motifs of certain membrane bound desaturases, and indicate that borage delta-6 desaturases have structural features distinct from the corresponding motifs of other membrane bound desaturases. Applicant also argues that a comparison of the borage and evening primrose delta-6 desaturases shows that they have virtually the same histidine-rich motifs, which are distinct from the corresponding motifs in other desaturases. Applicant asserts that only a representative number of species are required, and points to another six plant delta-6 desaturase

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sequences that were later identified and provided in Exhibits 1-7 also have virtually identical histidine motifs and corroborate that the present inventor had possession of the full scope of the present invention at the time of filing.

2. The Examiner maintains that the histidine motifs provided in Exhibits 1-7 demonstrate that the motifs are similar among plant species, but not identical.

3. Applicant states that to advance prosecution of the case that Claim 48 and new claim 60 are drawn to plant delta-6 desaturases comprising all three histidine-rich motifs, and claim 59, as amended, recites that the claimed plant delta-6 desaturase coding sequence hybridizes under the specified conditions to a plant delta-6 desaturase which comprises SEQ ID NO: 6, 12 and 20.

Applicant further argues that the fact that there are numerous motifs identical to any of SEQ ID Nos 6, 12 or 20 is irrelevant to the present invention, since they do not have all three of the motifs.

4. The Examiner maintains that the way in which claim 48 has been amended is such that the claimed nucleic acid need only have one of SEQ ID NO: 6, 12 or 20, because applicant has inserted in the claim the phrase “at least one of” with regard to SEQ ID NO: 6, SEQ ID NO: 12 and SEQ ID NO: 20. In addition, new claim 60 is drawn to a nucleic acid that will hybridize to a nucleic acid encoding SEQ ID NO: 6, 12 and 20. However, no stringency conditions are provided, and the claim does not require that the nucleic acid comprises SEQ ID NO: 6, 12 and 20.

5. In addition, as stated in the last office action, the described motifs are recited in claims 48 and 49 by SEQ ID NO: 6, 12 and 20. However, a search of these motifs indicated that the motifs of SEQ ID NO: 12 and 20 are present in a multitude of other genes that do not code for delta-6

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desaturases. The search of SEQ ID NO: 12 identified more than 1000 DNA sequences having that identical motif. The search of SEQ ID NO: 20 identified more than 250 DNA sequences having that identical motif. Identical matches to SEQ ID NO: 6 were all delta-6 desaturases. However, sequences that had the sequence of SEQ ID NO: 6 with one substitution included sphingolipid desaturases, and those with two substitutions included a human G protein coupled receptor and a mouse anion transporter. Therefore, the recitation of these motifs, and particularly any one of these motifs, is not sufficient to describe a delta-6 desaturase. In addition, the Examiner maintains that for new claim 60, in view of the large number of sequences that are homologous to these motifs and given that no stringency conditions for hybridization and wash are provided, the claimed invention is not adequately described.

6. Claims 48, 51-58 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acid sequences that encode a delta-6 desaturase from the plant species: evening primrose and borage, and from *Synechocystis* and cyanobacteria, does not reasonably provide enablement for any delta-6 desaturase from any species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action.

7. Applicant's arguments filed February 3, 2006 have been fully considered but they are not persuasive. Applicant asserts that given the assay for determining activity, and given that hybridization techniques are well known in the art, and in view of the structural features of the histidine rich boxes, those skilled in the art would be able to identify a plant delta-6 desaturase

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gene. Applicant points to the references of Sperling et al, Girke et al and Garcia-Maroto et al as teaching the isolation of additional delta-6 deaturase genes by making primers to the sequences encoding or surrounding the histidine-rich domains, and a yeast gain-of function assay.

8. The Examiner maintains that it would require undue experimentation to make and/or use the invention as broadly claimed for the reasons of record in the last office action, and for the reasons discussed above with regard to the written description rejection. Applicants are arguing limitations that are not in the claims. The claims are not drawn to nucleic acids isolated by hybridization to sets of primers, and the primers used in the post-filing date references submitted are not specifically set forth in the specification.

The claims are deemed free of the prior art given that a delta-6 fatty acid desaturase coding sequence was not taught or suggested by the prior art of record.

#### ***Double Patenting***

9. The rejection of claims 48 and 58-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 5,614,393 is withdrawn in view of the filing of a Terminal Disclaimer.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Elizabeth F. McElwain, Ph.D.  
Primary Examiner  
Art Unit 1638

EFM